REMARKS

The claims have been amended to correct typographical errors and to add new claims. No new matter has been added to the patent application.

This is in response to the Office Action dated January 11, 2008. Claims 55, 85, 91, 117, 119 and 124 were rejected by the Examiner.

Claims 55, 85, 91, 117, 119 and 124 were rejected under 35 U.S.C. §112, second paragraph. Applicant respectfully traverses this rejection.

Applicant respectfully submits that the language "substantially pure" is sufficiently definite to one skilled in the art, and one would know that what is meant by it is that the substance is pure enough to work as intended. Further, there is a reference in the examples to 80% purity and 81% purity at page 12, lines 23-26. There is also a reference to 98% purity at page 6, lines 30-32. These examples indicate what might be considered to substantially pure, whether for these specific examples or other similar substances.

Claims 55, 85, 91, 117, 119 and 124 were rejected under 35 U.S.C. §112, first paragraph. Applicant respectfully traverses this rejection.

The limitation "the fatty acid consists of at least 20 carbon atoms" appears throughout the patent application as filed, including for example in the Summary of the Invention at page 3, line 21, Examples 4-7, and in claims 24, 25, and 120. The limitation "more than 19" is simply another way to say "at least 20" and thus is also supported by the application as filed.

Claims 55, 85, 91, 117, 119 and 124 were rejected under 35 U.S.C. §112, second paragraph. Applicant respectfully traverses this rejection.

The terms "derivative" and "precursor" are commonly used in the art and it is respectfully submitted that one of ordinary skill in the art would know what they mean and what the claims cover.

Regarding the monoester, it is respectfully submitted that one of ordinary skill in the art, reviewing the claims and specification (especially the examples) would understand that a single molecule is being claimed.

Claims 55, 85, 91, 117, 119 and 124 were rejected under 35 U.S.C. §103(a) as being unpatentable over Alemany et al. (U.S. Patent No. 5,798,348) in view of Allison et al. (U.S.

Patent Application Publication No. 2006/0083778), and further in view of Zhu et al. (Carcinogenesis, 1998, 19, page 1-27). Applicant respectfully traverses this rejection.

Allison et al. is not available to be used against the present claims in a rejection under 35 USC Section 103(a). Allison et al. was not published until 20 April 2006. Its corresponding PCT application was published in November 2003, shortly before the present application was filed. The claims at issue in the present application are fully supported at least by US Provisional Patent Application No. 60/490,709, filed 29 July 2003; thus Alison et al. was not available in a published form prior to the time the claimed invention was invented by the present applicant, and thus cannot be used under 35 USC Section 103(a) to invalidate these claims. That is, applicant's claimed invention could not have been obvious to one of ordinary skill in the art at the time the invention was made by the Applicant herein by combining the teachings of Alemany, Zhu, and Allison et al., if Allison et al. was not available to the public at the time the invention was made.

Even if Allison et al. had been available at the time the invention was made, the present invention would still be patentable over these references.

Applicant amended the claims in the prior response to specify that the fatty acid contains at least 20 carbon atoms. Applicant distinguishes an Alemany reference (specifically, Life Sci, 1998: 62 (15): 1349-59 - identified in the IDS filed 23 June 2006 as Sanchis et al. - the prior response erroneously and inadvertently referred to this reference as "the Alemany reference" implying that it was US Patent No. 5,798,348) in the specification at page 8, lines 9-26, and page 9, lines 8-14. That reference (specifically, Life Sci, 1998: 62 (15): 1349-59) of Alemany discloses fatty acids of 18 or fewer carbon molecules. The applicant prefers fatty acids with more than 18 carbon molecules. The applicant has found that the higher carbon molecule compounds are more active and thus more effective for weight loss.

Applicant amended the claims in the prior response to specify that the estrogen derivative is a 2 hydroxy derivative. The 2-hydroxy molecule is of particular importance. The estrogen molecule, by itself in a biological system, has been reported to have positive carcinogenic properties. With a hydroxyl group in position 2, the molecule is believed to be anti-carcinogenic. If the hydroxyl group is in position 16, the resulting compound is believed

to be more carcinogenic than the unmodified molecule. Examples 8-12 show the significance of the 2-hydroxy molecule.

The Alemany reference mentioned in the present specification at page 8, lines 9-26, and page 9, lines 8-14 teaches against applicant's inventions as claimed (see discussion above). Since this Alemany reference is later in time than the Alemany patent used in the present rejection, it would be more likely followed since it is the later pronouncement by Alemany on this subject.

Applicant respectfully disagrees with the Examiner that "Zhu et al. suggest 2-hydroxyestrone is a major metabolite of estrone". Zhu et al. lists 2-hydroxyestrone as one of many metabolites of estrone (see table 1 of Zhu et al.).

Applicant asserts that Zhu,et al. suggests that "certain estrogen metabolites may function as chemical mediators or as secondary hormones with **unique functions**." Zhu, et al. (Carcinogenesis, vol. 19, no. 1, pp.16-17, emphasis added). Zhu, et al. specifically points out that estrogen metabolism "not only alters the intensity of estrogen action but may also alter its profile of physiological effects," that this is an "underexplored area in need of more attention" and that further research "may lead to an enhanced understanding of estrogen action." Zhu, et al. (Carcinogenesis, vol. 19, no. 1, p. 17).

With regard to 2-hydroxyestradiol, Zhu et al. reports that it is of "considerable interest that there are large interindividual differences in the 2-hydroxylation of estradiol or estrone by human liver samples and these inter-individual differences may be reflected by person-to-person differences in estrogen action in different individuals." Zhu, et al. (Carcinogenesis, vol. 19, no. 1, p. 3). Zhu et al. continues that it will be of "interest **to identify** the cytochrome P450 isoforms that have high activity for the peroxidatic formation of catechol estrogens in liver or estrogen target tissues, and **to ascertain the physiological significance** of this peroxidatic pathway *in vivo*" and "the concentrations of unconjugated 2-hydroxyestradiol and 2-hydroxyestrone metabolites are very low in the systemic circulation and in several tissues, which is probably due to rapid conjugative metabolism followed by urinary excretion." Zhu et al. (Carcinogenesis, vol. 19, no. 1, p. 4, emphasis added).

With regard to estrogen fatty acid esters, Zhu et al. suggests that it will be "**of**

considerable interest to advance our knowledge on the formation, storage and, in particular, subsequent hydrolysis of estrogen-fatty acid esters" and "**of interest to study the factors** (endogenous or exogenous) that regulate the synthesis and cleavage of estrogen fatty acid esters since factors influencing the formation and hydrolysis of estrogen fatty acid esters in liver and in extrahepatic target cells may profoundly affect the intensity and duration of estrogen action in the body." Zhu et al. further states that "**the significance** of this effect on estrogen's hormonal action **remains to be elucidated**." Zhu et al. (Carcinogenesis, vol. 19, no. 1, p. 14, emphasis added).

Applicant respectfully submits that a reference which continually suggests and teaches additional research in order to determine the significance, to advance the knowledge and to ascertain the physiological significance of biochemical functions cannot provide a valid basis for a rejection of Applicant's invention as claimed. There is no explicit or implied teaching, suggestion, or motivation for one of ordinary skill in the art to do anything other than more research.

As provided in MPEP 706.02(j) and 2143, first, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings; second, there must be a reasonable expectation of success, and finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art and not based on applicant's disclosure. In re Vaeck, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

The mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination. In re Mills, 916 F.2d 680, 16 USPQ2d 1430 (Fed. Cir. 1990); MPEP 2143.01. A statement that modifications of the prior art to meet the claimed invention would have been "'well within the ordinary skill of the art at the time the claimed invention was made'" because the references relied upon teach that all aspects of the claimed invention were individually known in the art is not sufficient to establish a prima facie case of obviousness

without some objective reason to combine the teachings of the references. Ex parte Levengood, 28 USPQ2d 1300 (Bd. Pat. App. & Inter. 1993); MPEP 2143.01.

Applicant respectfully submits that the application is in condition for allowance. A Notice of Allowance is hereby respectfully requested.

Should the Examiner feel that a telephone conference would advance the prosecution of this application, she is encouraged to contact the undersigned at the telephone number listed below.

The requisite fees of $525 are being charged to Deposit Account No. 50-0694. Applicant respectfully petitions the Commissioner for any extension of time necessary to render this paper timely. Please charge any fees due or credit any overpayment to Deposit Account No. 50-0694.

Respectfully submitted,

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